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510K Summary of Safety & Effectiveness

Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories

Company:

Prosurg, Inc
2193 trade Zone blvd
San Jose CA 95131

Contact:

Ashvin Desai ,
Mgr Regulatory Affairs
Tel: (408) 945 -4044

Date Preparaed: June 29, 2007

Device Name: Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories

Predicated Devices: Synthes Craniofacial Plate and Screw System (Ref: # K050608)
Inion CPS Baby 1.5 Bioabsorbable Fixation System (Rf: # K051341)
BONAMATES Series cleared by FDA (Ref:#K040650)

Device Description:

Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories consists of single use, bioabsorbable Bone Fixation plates, meshes, fixation screws, fastners and tacks designed for use in trauma and reconstructive procedures for craniofacial skeleton, mid-face, maxilla and chin in adult and children.
The single use, bioabsorbable Bone fixation plates and meshes are offered in various sizes and configurations to meet anatomical needs of the patients. The Xsorb™- Bioabsorbable Craniofacial Bone Fixation pltaes & screws / wires are made from bioabsorbable co-polymer material of Poly (L –Lactide & DL-Lactide-70:30 or 85:15) . The bone plates and meshes are designed to be used with 1.8mm screws and 2.1 mm emergency screws for trauma and reconstructive procedure. The bioabsorbable screws can be tightened with 1.8mm screw driver.

Indications for Use:

General Indication for Use:

Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, mid-face, maxilla and chin in adult and children.

Specific Indications for Use:

- Fractures of the cranium, mid-face, maxilla and chin.
- Infant craniofacial surgery (i.e. Craniosynostosis, Congenital malformations)
- Le Forte (I, II, III) Osteotomies.

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- Pediatric Reconstructive procedures of Cranial facial Skeleton
- Orthognathic or Reconstructive procedures of mid-face, maxilla & chin.
- Facial Craniotomy flap fixation.

Comparison of technological Characteristics:

Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories for use in trauma and reconstructive procedures in the craniofacial skeleton, mid-face, maxilla and chin in adult and children are substantially equivalent to the predicated devices, Synthes Craniofacial Plate and Screw System, Inion CPS Baby 1.5 Bioabsorbable Fixation System, BONAMATES Series cleared by FDA under 510k application # K050608, K051341 and #K040650 respectively. The FDA regulatory clearance report, 510k application and product information details regarding predicated device is attached herewith for your review and consideration. Please review the comparison matrix outlining the Product specifications, Material compatibility and Indications for Use for the proposed device with predicated device. Please note that the proposed product is substantially equivalent to predicated devices in product design, materials, packaging and intended use.

Performance Data:

Preclinical testing was performed to ensure that the Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories products performs as intended when used according to the instructions for use. Laboratory product testing has indicated that the Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories has demonstrated satisfactory performance for its intended applications. Mechanical testing of the devices also demonstrated that the tensile strength, breakage force and degradation time for the device are equal or more than the predicated devices and are satisfactory for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2007

Mr. Ashvin Desai
Manager, Regulatory Affairs
Prosurg, Incorporated
2193 Trade Zone Boulevard
San Jose, California 95131

Re: K070737
Trade/Device Name: Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: June 29, 2007
Received: July 3, 2007

Dear Mr. Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

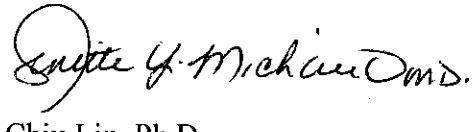
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070737

Indications for Use

510(k) Number (if known): **K070737**

Device Name: **Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories.**

Indications for Use:

General Indication for Use:

Xsorb™- Bioabsorbable Craniofacial Bone Fixation System & Accessories is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, mid-face, maxilla and chin in adult and children.

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- Pediatric Reconstructive procedures of Cranial facial Skeleton.
- Orthognathic or Reconstructive procedures of mid-face, maxilla & chin.
- Facial Craniotomy flap fixation.

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ision Sign-Off)
...vision of Anesthesiology, General Hospital,
...fection Control, Dental Devices

...10(k) Number: K070737